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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,038	07/11/2003	Peter Andersen	SS15AUSA	5215
270. 7590 02/22/2010 HOWSON & HOWSON LLP 501 OFFICE CENTER DRIVE SUITE 210 FORT WASHINGTON, PA 19034				
EXAMINER				
SWARTZ, RODNEY P				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
02/22/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary

Application No.

10/617,038

Applicant(s)

ANDERSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32 and 34-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-40 and 42 is/are allowed.
- 6) ☒ Claim(s) 29-32, 34-37, 41 and 43-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Office Action, received 8 December 2009, is acknowledged. Claims 9, 10, 12, 13, 16, 17, 24-28 and 33 have been cancelled. Claims 30, 31, 32, 38, 39 and 40 have been amended. New claims 41-47 have been added.
2. Claims 29-32 and 34-47 are pending and under consideration.

Rejections Moot or Withdrawn

3. The rejection of claims 12, 13 and 28 under 35 U.S.C. 102(b) as being anticipated by Horwitz (U.S. Pat. No. 5,108,745) is moot in light of the cancellation of the claims.
4. The rejection of claims 9, 10, 12, 13, 16, 17, and 24-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is moot in light of the cancellation of the claims.
5. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for relationship of polypeptide with antigen, is moot in light of the cancellation of the claim.
6. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of antigen and prophylactic activity, is moot in light of the cancellation of the claim.
7. The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite for "such as", is moot in light of the cancellation of the claim.
8. The rejection of claim 33 under 35 U.S.C. 112, second paragraph, as being indefinite for phrasing of claim, is moot in light of the cancellation of the claim.
9. The rejection of claim 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is moot in light of the cancellation of the claim.
10. The rejection of claims 10, 17 and 24-27 under 35 U.S.C. 112, second paragraph, as being indefinite for phrasing of claim, is moot in light of the cancellation of the claims.

11. The rejection of claims 31 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for relationship of polypeptide with antigen, is withdrawn in light of the amendment of the claims.
12. The rejection of claim 30 under 35 U.S.C. 112, second paragraph, as being indefinite for how each sequence has SEQ ID NO:24, is withdrawn in light of the amendment of the claim.
13. The rejection of claim 32 under 35 U.S.C. 112, second paragraph, as being indefinite for improper Markush grouping, is withdrawn in light of the amendment of the claim.
14. The rejection of claim 38 under 35 U.S.C. 112, second paragraph, as being indefinite for "peptides" and "polypeptides", is withdrawn in light of the amendment of the claim.
15. The rejection of claim 40 under 35 U.S.C. 112, second paragraph, as being indefinite for improper Markush grouping, is withdrawn in light of the amendment of the claim.

Rejections Maintained

16. The rejection of claims 29-32 and 34-37 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained.

Applicants argue that the specification sufficiently teaches vaccines comprising ≥ 1 polypeptide of SEQ ID NOs 1-45 in Table 1, pages 8 and pages 32-33, and "examples are not necessary to support the adequacy of a written description".

The examiner has considered applicants' argument, but does not find it persuasive. Table 1, beginning on pages 8-14 of the instant specification, is merely a listing entitled "Amino acid sequences of selected low oxygen induced antigens". Pages 32-33, constitute a hoped for result, i.e., that the antigens will be vaccines. The only actual examples do not utilize these sequences, but whole BCG, ESAT6, Rv2031c, Rv0569 and two fragments of Rv2031c. Thus, the specification does not reasonably convey to one skilled in the relevant art that the inventors, at

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the time the application was filed, had possession of therapeutic vaccines against tuberculosis comprising one or more polypeptides having an amino acid sequence selected from the group consisting of SEQ ID NOs 1-45.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Newly added claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly added claim is drawn to the vaccine of claim 39, wherein said at least one fusion partner is a different said one or more polypeptide.

It is unclear from what the fusion partner is different. Is it different from the fusion partner or different from the initial polypeptides?

18. Newly added claims 43-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added claims are drawn to a therapeutic vaccine comprising ≥ 1 polypeptide selected from SEQ ID NOs:1-45.

The specification provides vaccine examples of only whole BCG, ESAT6, Rv2031c, and Rv0569, and two fragments of Rv2031c. The specification does not teach any vaccines comprising the other sequences in the listing of SEQ ID NOs:1-45.

Therefore the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., vaccines comprising ≥ 1 polypeptide selected from SEQ ID NOs:1-45.

Conclusion

19. Claims 29-32, 34-37, 41 and 43-47 are finally rejected.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

February 20, 2010